

REMARKS

As the Examiner indicates, Claims 29, 31, 33, 34, 36, 39-41, 46, 49, 51 and 61-77 have been examined on the merits. Claims not elected have been withdrawn pending the filing of a divisional application or applications.

The listed claims were each rejected under 35 U.S.C. § 112 for alleged indefiniteness. Failure to particularly point out and distinctly claim various features of the invention are alleged by the Examiner in most cases, and indefiniteness based on improper antecedent bases in others. Several informalities are also noted by the Examiner.

Each of the aforelisted claims rejected for indefiniteness have been amended to overcome these criticisms. Likewise, formal objections have been obviated by amendment.

Rejections on the merits of claims take two forms. First, each of the aforelisted claims is rejected under 35 U.S.C. § 103(a) over Chopra WO 01/52822 A1 in view of Motoyama et al. Second, these claims have also been provisionally rejected on grounds of obviousness-type double patenting over claims 16-19 pending in U.S. application 11/586511.

With respect to the 35 U.S.C. § 103(a) rejections, the present invention relates to a reduced coenzyme Q₁₀ containing composition which comprises reduced coenzyme Q₁₀, a polyglycerol fatty acid ester, and a fat or oil and/or a polyol. This composition has the good stability of reduced coenzyme Q₁₀ and the high-level absorbability in the living body thereof, simultaneously. Specifically, the addition of the polyglycerol fatty acid ester enhances absorbability of reduced coenzyme Q₁₀ in the living body and hardly inhibits the reduced coenzyme Q₁₀-stabilizing effect of the fat or oil and/or polyol.

As described on page 5, lines 14-24 in the specification, the applicants discovered that while the addition of Tween and Span species (surfactants (emulsifiers)) in wide use markedly decreases the above-mentioned reduced coenzyme Q₁₀-

stabilizing effect of fat or oil and/or polyol, the addition of polyglycerol fatty acid esters surprisingly has little influence on the stabilizing effect of fat or oil and/or polyol.

On the other hand, Chopra relates to a composition comprising ubiquinol and an amount of a reducing agent effective to reduce or eliminate the oxidation of that ubiquinol to ubiquinone; that composition further comprising an amount of a surfactant or vegetable oil or mixtures thereof and optionally, a solvent, effective to solubilize said ubiquinol and said reducing agent. As the Examiner recognizes, Chopra does not disclose the reduced coenzyme Q₁₀-containing composition comprising the polyglycerol fatty acid ester of the present invention.

Motoyama relates to a pharmaceutical composition which provides a high-degree of bioavailability of cyclandelate when administered orally. The composition consists of a mixture of (a) a polyglycerol ester of an unsaturated fatty acid or mixtures thereof and (b) cyclandelate. Motoyama only describes that the polyglycerol ester of an unsaturated fatty acid is used in order to facilitate the absorptivity of the drug. Thus, Motoyama neither discloses nor suggests that the polyglycerol ester of an unsaturated fatty acid hardly inhibits the reduced coenzyme Q₁₀-stabilizing effect of fat or oil and/or polyol.

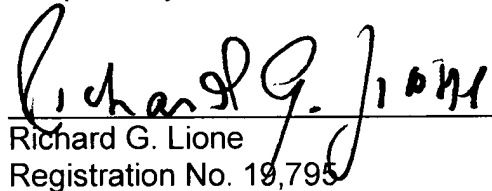
It is thus abundantly clear that neither Chopra nor Motoyama disclose nor suggest that the composition can have the good stability of reduced coenzyme Q₁₀ and the high-level of absorbability thereof in the living body by the constitution of the present invention. Accordingly, the present invention could not have been suggested by one skilled in the art from the combination of Chopra and Motoyama, except perhaps by chance or hindsight.

With respect to obviousness-type double patenting rejections, claims 16-19 of copending application No. 11/586511 relate to a stable composition comprising reduced coenzyme Q₁₀. The composition comprises ascorbic acid or a related compound thereof together with the reduced coenzyme Q₁₀, an oil or fat, a polyglycerol fatty acid ester with a polymerization degree of glycerol being no lower than 3 and/or a condensed ricinoleic acid polyglyceride. In contrast, the present application defines a

selective invention, in which more excellent stabilizing effect can be obtained by limitation of the polymerization degree of glycerol to no lower than 3. This is shown in Example 1, and Table 1 of the copending application. As such, the invention claimed in the present application is not obvious from that of the copending application.

Finally, from a housekeeping standpoint, applicants respectfully request appropriate acknowledgment of "Priority Under 35 U.S.C. 119" items in the Office Action Summary. It is requested that numbered paragraph 12 in the Office Action Summary, boxes 12, 12(a) and 12(a)(3) be checked.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Richard G. Lione", is written over a horizontal line.

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